

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effects of single Platelet-Rich Plasma local injection on pain, symptom severity, functional state and electrodiagnostic findings in women with mild and moderate Carpal Tunnel Syndrome, A clinical trial

Protocol summary

Summary

Objectives: This study is designed to indicate the short term effects of Platelet-Rich Plasma (PRP) injection on VAS score, symptom severity and functional status based on Boston questionnaire and electrodiagnostic findings of women with idiopathic mild and moderate Carpal Tunnel Syndrome (CTS). **Study Design:** This study is a non-blind randomized clinical trial. Randomization will be done by computer generated random numbers. **Setting and conduct:** A total of 41 patients will be randomly assigned to two groups of control, only using a wrist splint, and PRP that received wrist splints along with a single local injection of in the carpal tunnel. **Participants:** Participants are women referring to the physical medicine and rehabilitation clinics at Shahid Modarres Hospital during 2016 with a diagnosis of mild and moderate idiopathic CTS aged 20 to 65 without any comorbidities such as thyroid disease or diabetes mellitus. **Interventions:** Both groups will use the same prefabricated hand wrist splint for CTS along with PRP group will be treated with a single injection of 1 ml of PRP plus 0.5 ml lidocaine 1% in the carpal tunnel. **outcome measures:** At the beginning and 10 weeks after the intervention, outcome measures which are Pain visual analog scale (VAS), (BQ-SYMPT) Boston/Levine symptom severity scale and Boston/Levine functional status scale (BQ-FUNC), median nerve sensory peak latency and median nerve will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041513442N13**
Registration date: **2017-06-19, 1396/03/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Department

Expected recruitment start date

2017-02-22, 1395/12/04

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of single Platelet-Rich Plasma local injection on pain, symptom severity, functional state and electrodiagnostic findings in women with mild and moderate Carpal Tunnel Syndrome, A clinical trial

Public title

Effects of Platelet-Rich Plasma local injection in

treatment of women with mild and moderate carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patient with mild and moderate CTS confirmed by the presence of one or more of the following standard electrophysiological criteria: 1- prolonged distal motor latency (DML) (abnormal response is more than 4.2 millisecond) of Median nerve and 2- prolonged antidromic distal sensory latency (DSL) to the third digit (abnormal response is more than 3.6 millisecond); Exclusion criteria: Pregnancy; Severe degree CTS; Background metabolic diseases such as: diabetes mellitus; hypothyroidism; rheumatoid arthritis; Previous history of corticosteroid injection in Carpal Tunnel Syndrome; Severe atrophy of thenar muscles; cervical radiculopathy or significant polyneuropathy; Unwillingness to participate in the present study; patient younger than 20 or older than 65 years old; history or presence of cancer or malignant disorders; presence of immunosuppressive, autoimmune and platelet disorders; treatment with anticoagulant and anti-platelet medications 10 days before injection; use of NSAIDs 2 days before injection; use of systemic corticosteroids 2 weeks before PRP injections; hemoglobin measures of less than 12 g/dl and platelet counts of less than 150,000 per micro liter

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **41**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
randomization via computer generated random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahid Beheshti University Of

Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yaman Street, Chamran Highway Tehran Iran, Islamic Republic Of Iran

City

Tehran

Postal code

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

IR.SBMU.MSP.REC.1395.382

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Mononeuropathies of upper limb

Primary outcomes

1

Description

pain

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Visual Analog Scale, that is from 0-10 and zero (0) means that you did not have any pain and ten (10) means that you had the worst pain imaginable

Secondary outcomes

1

Description

median CMAP distal latency

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Electrodiagnostic study

2

Description

symptom severity

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Boston/Levine symptom severity scale

3

Description

median SNAP peak latency

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Electrodiagnostic study

4

Description

Functional Status

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

boston questionnaire

Intervention groups

1

Description

Single injection of 1 ml of PRP with 0.5 ml lidocain 1% in carpal tunnel and prefabricated hand wrist splint in neutral position for CTS

Category

Treatment - Drugs

2

Description

Prefabricated hand wrist splint in neutral position for CTS

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Modarres Hospital, Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Street address

Shahid Modarres Hospital, Kaj Square, Saadat Abad street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Street address

Shahid Beheshti University of Medical sciences, next to Taleghani Hospital, yaman street, Chamran Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Leila Bagherzadeh

Position

Resident in physical medicine and rehabilitation

Other areas of specialty/work**Street address**

Shahid Modarres Hospital, Kaj square, Saadat Abad street, Tehran

City

Tehran

Postal code**Phone**

+98 21 2273 1112

Fax**Email**

leila_bagherzade@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Other areas of specialty/work**Street address**

Shahid Modarres Hospital, Kaj Square, Saadat Abad
street, Tehran

City

Tehran

Postal code

Phone

+98 21 2273 1112

Fax

Email

a_raeissadat@sbmu.ac.ir

Web page address

City

Tehran

Postal code

Phone

+98 21 2273 1112

Fax

Email

leila_bagherzade@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti Univeraity of Medical Sciences

Full name of responsible person

Leila Bagherzadeh

Position

Resident in physical medicine and rehabilitation

Other areas of specialty/work

Street address

Shahid Modarres Hospital, Kaj square, Saadat Abad
street, Tehran

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty